

	System Level Manual Regulatory Standards Division, AMA-200	Document # QP 221	Revision Original
Title: Control of Nonconforming Products Procedure			Page 1 of 2

REVISION HISTORY			
Rev	Description of Change	Author	Effective Date
A	Original	JLA	05/26/2003

REFERENCE DOCUMENTS	
Document Number	Document Title
QMS 200	Regulatory Standards Quality Systems Manual

Documents referenced in this procedure are applicable to the extent specified herein.

1. Purpose

This procedure establishes the process for the control of nonconforming products used by AMA-200 in accordance with the AMA-200 Quality System Manual.

2. Scope

This procedure is applicable to all Product Lines providing products governed by the requirements specified within the AMA-200 Quality System Manual.

3. Definitions and Acronyms

Concession	The release of a product having a known nonconformity with the full knowledge of the customer.
Nonconformity	The non-fulfillment of a specified requirement

4. Flowchart

There is no flowchart required for this document

5. Responsibilities

- 5.1 The **Responsible Manager** shall ensure that a product having a known nonconformity is not released to a customer prior to corrective action, except under concession (See 6.1.1).
- 5.2 All AMA-200 employees are authorized and responsible to report nonconformities immediately upon detection.

6. Procedure

- 6.1 No product having a detected nonconformity shall be released to a customer by any AMA-200 product line, except as follows:
 - 6.1.1 A customer may accept a product with a known nonconformity under concession. The customer must accept the product under their signed

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letterhead including a statement that they are fully aware of the nonconformity. The letter must include the stated requirement with a detailed explanation of how the product does not conform.

- 6.2 To avoid the unintended use of an AMA-200 product, all nonconformities shall be **identified and controlled**.
- 6.3 Nonconformities may be **identified** by any AMA-200 employee, during the course of production, through the audit process or by the customer after delivery.
- 6.4 Nonconformities shall be reported and **controlled** using the Corrective Action process found in QMS 200 ([QMS 200, 8.5.2](#) ;and [QP 117](#)).
- 6.5 When corrective action is taken regarding a nonconformity, it shall be subject to re-verification to demonstrate conformity to the applicable requirements. Re-verification shall be accomplished in accordance with the requirements of QMS 200 ([QMS 200, 8.5.2](#);and [QP 117](#)).
- 6.6 If a nonconformity is detected after delivery or initial use, AMA-200 shall take the appropriate action to eliminate the nonconformity or its effects.
- 6.7 Records of nonconformities, including subsequent actions taken and concessions, shall be maintained by the Internal Audit Program Manager in accordance with [QMS 200](#).

7. Metrics

Metrics for this procedure will be determined by the AMA-200 Leadership Team in accordance with the Management Review Process.

8. Quality Records

Quality Records for this document are listed in the table below. These records shall be generated and managed in accordance with AMA-200 Quality Records procedures.

Verifying Document Type or Number	Title	Retention Time
QF 117	Quality Corrective Action Request (QCAR)	Five Years

Quality documents, in blank form, are found in [Appendix 1](#) of the AMA-200 QMS.